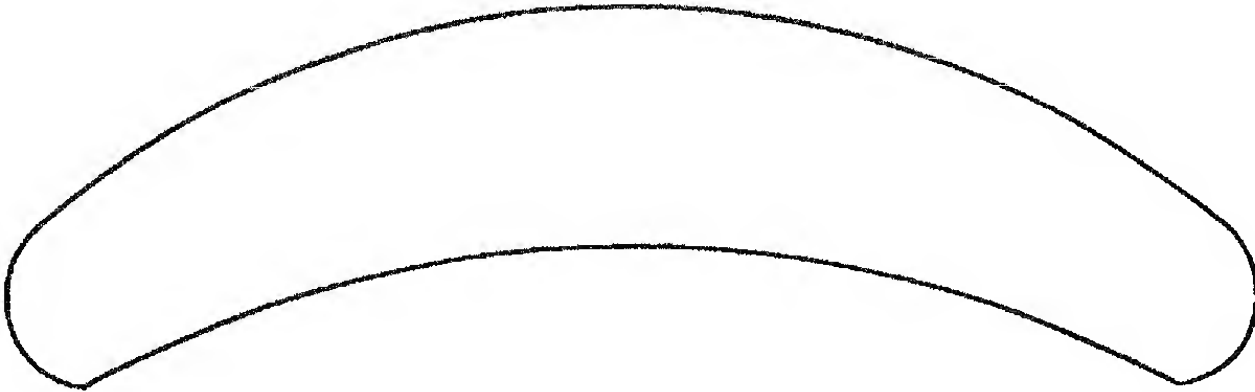




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(21) International Application Number: PCT/DK98/00419 (22) International Filing Date: 25 September 1998 (25.09.98) (30) Priority Data: 1125/97 30 September 1997 (30.09.97) DK (71) Applicant (for all designated States except US): COLOPLAST A/S [DK/DK]; Høltedam 1, DK-3050 Humlebaek (DK). (72) Inventor; and (75) Inventor/Applicant (for US only): MARCUSSEN, Jan [DK/DK]; Kirkestien 40, DK-2630 Taastrup (DK). (74) Common Representative: NILAUSEN, Kim; Coloplast a/s, Patent Dept., Høltedam 1, DK-3050 Humlebaek (DK).		(81) Designated States: AL, AM, AT, AT (Utility model), AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, CZ (Utility model), DE, DE (Utility model), DK, DK (Utility model), EE, EE (Utility model), ES, FI, FI (Utility model), GB, GE, GH, GM, HR, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (Utility model), SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>
(54) Title: A DRESSING (57) Abstract <p>A dressing for covering a portion of the anatomical surface of a living being, said dressing being able to adhere to the skin, the mucosa and/or a wound on a protruding portion of a living being without exposing the skin to a significant stress after application and said dressing comprising a substantially water-impervious film and a skin-friendly adhesive, which dressing has a low modulus allowing and easy deformation during application but yet a sufficiently high elasticity to essentially prevent deformation of wrinkles after application, wherein the dressing is optionally covered in part or fully by one or more release liners or cover films to be removed before or during application and wherein the dressing has the general form of a boomerang facilitates the perfect adaptation during application to cover cracks at the tip of e.g. a finger or toe at the edge of the nail.</p> 		

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TITLE

A dressing

FIELD OF THE INVENTION

The present invention relates to dressings, in particular dressings for covering a
5 portion of the anatomical surface of a living being, the use of a film being able to
adhere to the skin for forming such dressings and a method of treating a portion
of the anatomical surface of a living being, especially a protruding part of the
body.

BACKGROUND OF THE INVENTION

10 Conventionally, dressings for the treatment or prevention of wounds or pressure
sores or even unbroken skin are essentially flat dressings which are sufficiently
mouldable to be applied to flat or slightly curved areas of the body. Such flat
dressings are not very suitable for applying on protruding parts of the body or
joints such as elbows, heels or especially the tips of fingers or toes or parts of
15 the body having a very pronounced curvature such as the inter digital area as
they often wrinkle and focus stresses in the dressing often causing slipping of the
adhesive and unintended detachment of the dressing.

Published European patent application No. EP 0 676 183 A1 discloses conform-
able adhesive bandages which are stated to be extremely conformable, and yet
20 resilient enough to maintain its shape after being subjected to forces caused by
movement of the wearer. The bandages contain at least three elements: the
backing material, which protects the wound-covering portion of the bandages;
the wound covering portion of the products which contacts the wound and
provides a reservoir for the wound exudate; and the adhesive composition, which
25 holds the product in place around the wound. Furthermore it is stated that the
recovered energy of the bandage disclosed in EP 0 676 183 A1 should be
relatively high, so as to assure that the bandage will not permanently deform in
use. Such recovered energy built-in into a dressing or bandage will inevitably try

to retract it to its original shape if stretched during use and expose the skin to a significant stress which will cause nuisance to the user.

US patent No. 4,436,700 discloses pressure sensitive adhesive sheet materials such as tapes and surgical drapes, which are stated to be conformable and
5 having viscoelastic properties similar to human skin. Furthermore it is stated, that the materials exhibit stress relaxation with time, having relaxation properties to recover to near original unstressed length, when all stress is removed.

Published European patent application No. EP 0 457 977 A1 discloses a wound dressing comprising a pad of soft polyurethane foam, one surface layer of which
10 is hydrophilic and a backing layer of which is hydrophobic and a sheet or strip of a soft conformable polyether foam having an adhesive on one surface thereof, said dressing showing a sufficient elasticity to readily conform for extended periods of time to difficult areas such as elbow joints and knee joints.

US Patent No. 1,741,949 discloses an elastic polyetherester non woven web
15 formed by melt blowing fibres composed of a polyester.

A liquid plaster in the form of a solution of a polymer in ethyl acetate is known under the trade mark Nobecutan®. Such a plaster will naturally conform to the area onto which it is applied but is highly unsuitable for application on broken or irritated skin due to the content of ethyl acetate giving a severe local irritation.

20 Until now no reference discloses dressings being able to adhere to the skin, said dressing being flexible and mouldable so as to adapt to the contour of the part of the body to be covered and said dressing adhering to the skin and being able to adapt to and follow the movements of tips or roots of fingers or toes without exposing the skin to a significant stress after application and being applicable
25 directly on broken or irritated skin without unpleasant feeling.

One object of the invention is to provide a dressing being mouldable and flexible so as to be able to adapt to the contour of the part of the body to be covered and

said dressing adhering to the skin and being able to adapt to and follow the movements of the skin of especially tips or roots of fingers or toes.

Another object of the invention is to provide a dressing which may prevent e.g. wearing or abrasion damages, said dressing being provided with a surface which
5 may be adapted to the environment in which the dressing is to be used giving a longer effective time of use for the dressing between the change of the dressing.

A still further object of the invention is to provide processes for the preparation of such dressings.

The dressing of the present invention fulfils the above objects to a degree not
10 seen hitherto.

BRIEF DESCRIPTION OF THE INVENTION

The invention relates to a dressing for covering a portion of the anatomical surface of a living being, said dressing being able to adhere to the skin, the mucosa and/or a wound on any portion of a living being, and said dressing being
15 mouldable so as to adapt to the contour of the part of the body to be covered.

Furthermore, the invention relates to the use of a film being able to adhere to the skin, said film showing a low modulus when deformed and a deformation created before or during application of the dressing for forming a dressing for covering a portion of the anatomical surface of a living being.

20 The invention also relates to a method of treating a portion of the anatomical surface of a living being comprising applying a dressing being able to adhere to the skin, said dressing being mouldable so as to adapt to the contour of the part of the body to be covered.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention is explained more in detail with reference to the drawings in which

Fig.1 shows the contour of one embodiment of a "boomerang shaped" wound dressing according to the invention,

- 5 Fig.2 shows the contour of another embodiment of a "boomerang shaped" wound dressing according to the invention being relatively shorter and wider, and Fig.3 shows the contour of a further embodiment of a "boomerang shaped" wound dressing according to the invention being even more compact.

DETAILED DESCRIPTION OF THE INVENTION

- 10 The present invention relates to a dressing for covering a portion of the anatomical surface of a living being, said dressing being able to adhere to the skin, the mucosa and/or a wound on a protruding portion of a living being without exposing the skin to a significant stress after application and said dressing comprising a substantially water-impervious layer or film and a skin-friendly adhesive, which
- 15 dressing has a low modulus allowing an easy deformation during application but yet a sufficiently high elasticity to essentially prevent formation of wrinkles after application, wherein the dressing is optionally covered in part or fully by one or more release liners or cover films to be removed before or during application and wherein the dressing has the general form of a boomerang.
- 20 The dressing of the invention has surprisingly rendered it possible, when applying a dressing to a protruding part of the body to stretch the dressing to suit the size of the part of the body to be covered whereafter the dressing will adapt rather tightly to the contour of the part of the body to be covered and adhere to it without exposing the skin to a significant stress after application. The dressing
- 25 will adhere to the skin and follow later movements like a "second skin" which will ensure that the dressing does not tauten the skin or constrict parts of the body. Thus, the dressing of the invention shows a low modulus against deformation and retains a sufficient elasticity to follow the movements of the skin without formation of wrinkles. The reduced stress will give a long wear time and the

5 dressing of the invention only needs to be changed when it is "technically necessary" and many changes due to slipping are avoided. The general form of a boomerang facilitates the perfect adaptation during application to cover skin abnormalities such as cracks at the tip of e.g. a finger at the edge of the nail or in the area around the root of a finger or a toe.

The dressing preferably has rounded ends and preferably has smooth edges without scratches or being frayed at the edge. This is especially preferred at the "end" portions thereof avoiding points of attack for initiating an unintended rolling-up of the dressing.

- 10 The modulus against deformation and elasticity of a dressing of the invention is a result of the combined properties of the substantially water-impervious layer or film and the skin friendly adhesive. Thus, in one extreme, the substantially water-impervious layer or film is elastic and the skin friendly adhesive is plastic, and in the opposite extreme, the substantially water-impervious layer or film is plastic,
15 and the skin friendly adhesive is elastic. Any combination of properties there between fulfilling the requirements will be suitable according to the invention.

The skin-friendly adhesive may be any skin-friendly adhesive known per se, e.g. an adhesive comprising hydrocolloids or other moisture absorbing constituents for prolonging the time of use. The adhesive may suitably be of the type
20 disclosed in those disclosed in GB patent specification No. 1 280 631, in DK patent specifications Nos. 127,578, 148,408, 154,806, 147,226 and 154,747, in EP published application Nos. 0 097 846 and 0 415 183, in SE published application No. 365,410, in WO publication No. 88/06894, in US patent specification No. 4,867,748, and in NO published application No. 157,686. Especially preferred
25 are the adhesives disclosed in US patent Nos. 4,367,732 and 5,051,259 and DK patent specification No. 169,711.

The water impervious layer or film may be of any suitable material known per se for use in the preparation of wound dressings e.g. a foam, a non-woven layer or a polyurethane, polyethylene, polyester or polyamide film. In accordance with the
30 invention it has surprisingly been found that the use of a thinner backing layer or

film than is normally used when preparing medical dressings, an improved stretchability and adaptability is obtained at the same time as the modulus is reduced. These properties are obtained using the same load of adhesive as is conventionally used, and thus, the conventional properties of the adhesive are
5 retained as opposed to the case in which the load of adhesive was lowered giving a risk of insufficient tack and adhesive properties.

Using a layer or film having a low modulus allowing an easy deformation during application but yet a sufficiently high elasticity to essentially prevent deformation after application renders the dressing apt for application on e.g. tips or roots of
10 fingers or toes of various sizes as the dressing easily adapts to the actual curvature and still has a sufficient elasticity to ensure that the dressing does not form wrinkles and that it does not act ligating.

A dressing of the invention is thus especially apt for use on cracks on the tip of a finger or of a toe as it allows for a stretching of the dressing to be sufficiently
15 deformed to be able to cover a protruding part of the body e.g. a finger, whereafter the dressing quickly adapts to the protruding part of the body and adheres to the same. The dressing of the invention may be wrapped around an extremity such as a finger or stretched to cover e.g. the tip of a finger or a toe around the edge of the nail. The dressing of the invention is thus very suitable for covering
20 the area between fingers or toes and is also suitable for applying around the root of a finger or toe or in connection with joints such as elbows, knees or ankles where skin abnormalities such as cracks often occur.

The water impervious layer or film is preferably a low-friction flexible polymer film reducing the risk of unwanted stress in the area of the crack impeding the
25 healing of a crack on a very exposed site.

A suitable material for use as a water impervious film is a polyurethane. A preferred low friction film material is disclosed in US patent No. 5,643,187. A preferred thickness of this film is below 20 microns, more preferred about 12-18 microns, thus resulting in a significant decrease of the modulus, compared
30 to a film that is normally used when preparing medical dressings. An improved

stretchability and adaptability is obtained at the same time as the modulus is reduced.

The force used for stretching a dressing according to the invention 100 % is below 4.5 N, preferred below 2.5 N, more preferred about 0.6 to 1.8 N.

- 5 The dressing of the invention preferably has a ratio between the length and the width of from about 1.1:1 to about 12:1, more preferred from 1.5:1 to 10:1 and most preferred from about 1.5:1 to 6:1.

In order to ensure a suitable modulus in longitudinal direction, it is preferred that the width of the dressing does not exceed 20 mm, preferably not exceeding 12
10 mm.

The dressing of the invention preferably has bevelled edges in order to reduce the risk of "rolling-up" the edge of the dressing reducing the wear-time and thus disturbing and prolonging the healing of cracks normally healing slowly on tips of fingers or toes due to physical stress. A bevelling may be carried out discontinu-
15 ously or continuously in a manner known per se e.g. as disclosed in EP patent No. 0 264 299 or in US patent No. 5,133,821.

A protective cover or release liner may for instance be siliconized paper. It does not need to have the same contour as the dressing, e.g. a number of dressings may be attached to a larger sheet of protective cover. The protective cover is not
20 present during the use of the dressing of the invention and is therefore not an essential part of the invention.

Furthermore, the dressing of the invention may comprise a "non touch" grip known per se for applying the dressing to the skin without touching the adhesive layer. Such a non-touch grip is not present after application of the dressing.

- 25 It is advantageous to provide a dressing of the invention with components for treatment or prophylaxis of formation of wounds and/or skin abnormalities, e.g. with emollients or an active constituent e.g. retinoids for treating or preventing

formation of psoriasis, eczema, callous skin, corns, insect bites, acne or blisters. The dressing of the invention may also contain medicaments such as bacteriostatic or bactericide compounds, e.g. iodine, iodopovidone complexes, chloramine, chlorohexidine, silver salts, zinc or salts thereof, tissue-healing enhancing agents, e.g. RGD tripeptides and the like, enzymes for cleansing of wounds, e.g. pepsin, trypsin and the like, pain relieving agents, or agents having a cooling effect which is also considered an aspect of the invention.

A dressing according to the invention may be prepared by a manner known per se for the preparation of medical dressings by substituting the raw materials and it will be routine for the skilled in the art to adapt the process parameters to the actual materials.

The invention also relates to the use of a film having a low modulus being able to adhere to the skin for preparing a dressing for covering a portion of the anatomical surface of a living being, said dressing being able to adhere to the skin, the mucosa and/or a wound on a protruding portion of a living being without exposing the skin to a significant stress after application and said dressing comprising a substantially water-impervious layer or film and a skin-friendly adhesive, which dressing has a low modulus allowing an easy deformation during application but yet a sufficiently high elasticity to essentially prevent formation of wrinkles after application and wherein the dressing is optionally covered in part or fully by one or more release liners or cover films to be removed before or during application.

Further, the invention relates to a method of treating a portion of the anatomical surface of a living being, especially a protruding part of the body by applying a dressing for covering the portion of the anatomical surface of a living being, said dressing being able to adhere to the skin, the mucosa and/or a wound on a protruding portion of a living being without exposing the skin to a significant stress after application and said dressing comprising a substantially water-impervious layer or film and a skin-friendly adhesive, which dressing has a low modulus allowing an easy deformation during application but yet a sufficiently high elasticity to essentially prevent formation of wrinkles after application and wherein the dressing is optionally covered in part or fully by one or more release

liners or cover films to be removed before or during application. The conditions to be treated may be abnormalities like dry skin, cracks or the like.

DETAILED DESCRIPTION OF THE DRAWINGS

The invention is explained more in detail with reference to the drawings showing
5 a preferred embodiments of the invention in the form of a "boomerang shaped"
wound dressing especially suitable for finger cracks on the tip of a finger or toe.

The long and narrow embodiment shown in Fig. 1 is especially suitable for use
on fingers as this embodiment is especially suitable for winding around the tip of
a finger. When applying the dressing, the protective layer is removed and the
10 dressing is applied on the crack on tip of the finger or toe, and the two ends of
the dressing are stretched so that it follows the contour of the fingernail. When
the dressing is applied, the "boomerang shape" has shown to be very efficient for
a smooth adaptation to the contour of e.g. the limit of a finger nail.

The relatively more short and wider embodiments of "boomerang shaped"
15 wound dressings according to the invention shown in Fig. 2 and 3 are suitable
for use on thick fingers such as thumbs or especially for toes.

CLAIMS

1. A dressing for covering a portion of the anatomical surface of a living being, said dressing being able to adhere to the skin, the mucosa and/or a wound on a protruding portion of a living being without exposing the skin to a significant
5 stress after application and said dressing comprising a substantially water-impervious layer or film and a skin-friendly adhesive, which dressing has a low modulus allowing an easy deformation during application but yet a sufficiently high elasticity to essentially prevent formation of wrinkles after application, wherein the dressing is optionally covered in part or fully by one or more release
10 liners or cover films to be removed before or during application and wherein the dressing has the general form of a boomerang.
2. A dressing as claimed in claim 1, characterised in that it is intended for use on a protruding part of the body such as the tip of a finger or of a toe.
3. A dressing as claimed in claim 1 or 2, characterised in that the substantially
15 water-impervious film is a flexible polymer film having a low dynamic friction.
4. A dressing as claimed in claim 3, characterised in that the substantially water-impervious film is of polyurethane.
5. A dressing as claimed in any of claims 1 - 4, characterised in that the dressing has a ratio between the length and the width of from about 1.1:1 to about
20 12:1.
6. A method of treating a portion of the anatomical surface of a living being, especially a protruding part of the body by applying a dressing for covering the portion of the anatomical surface of a living being, said dressing being able to adhere to the skin, the mucosa and/or a wound on a protruding portion of a living
25 being without exposing the skin to a significant stress after application and said dressing comprising a substantially water-impervious layer or film and a skin-friendly adhesive, which dressing has a low modulus allowing an easy deformation during application but yet a sufficiently high elasticity to essentially prevent

formation of wrinkles after application, wherein the dressing is optionally covered in part or fully by one or more release liners or cover films to be removed before or during application and wherein the dressing has the general form of a boomerang.

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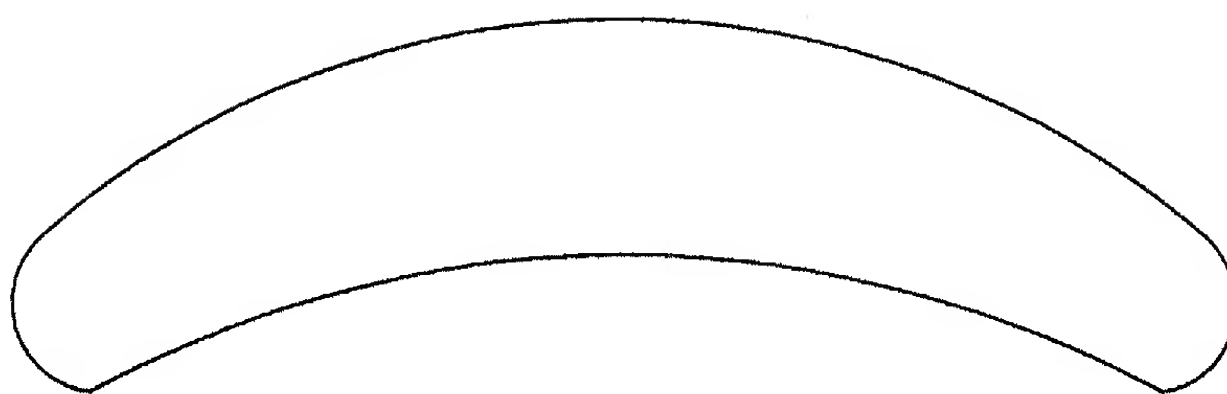


Fig. 1

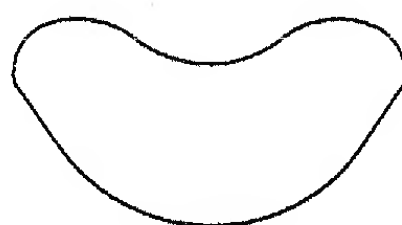


Fig. 2

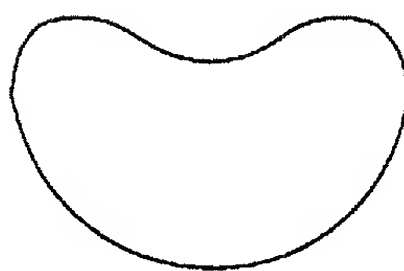


Fig. 3

INTERNATIONAL SEARCH REPORT

International application No.

PCT/DK 98/00419

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61F 13/02

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0051935 A2 (MINNESOTA MINING AND MANUFACTURING COMPANY), 19 May 1982 (19.05.82), page 7, line 1 - line 17; page 8, line 6 --	1-6
A	EP 0676183 A1 (JOHNSON & JOHNSON CONSUMER PRODUCTS, INC.), 11 October 1995 (11.10.95), column 3, line 13 - line 28; column 4, line 35, figure 1 --	1-6
A	US 4367732 A (F. POULSEN ET AL.), 11 January 1983 (11.01.83), column 1, line 9 - line 18; column 6, line 63 - line 65 -- -----	1-6

☐ Further documents are listed in the continuation of Box C.☒ See patent family annex.

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Date of the actual completion of the international search

21 January 1999

Date of mailing of the international search report

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INTERNATIONAL SEARCH REPORT
Information on patent family members

01/12/98

International application No.

PCT/DK 98/00419

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0051935 A2	19/05/82	SE 0051935 T3 AU 545844 B AU 7730381 A CA 1192825 A JP 1420620 C JP 57115480 A JP 62028994 B	01/08/85 20/05/82 03/09/85 14/01/88 17/07/82 23/06/87
EP 0676183 A1	11/10/95	AU 1632795 A BR 9501513 A CA 2146615 A CN 1116516 A JP 8038543 A BR 9501530 A CA 2146616 A CN 1116517 A JP 8038544 A	19/10/95 07/11/95 09/10/95 14/02/96 13/02/96 14/11/95 12/10/95 14/02/96 13/02/96
US 4367732 A	11/01/83	DE 3148097 A,C DK 147035 B,C DK 520980 A FR 2495473 A,B GB 2089351 A,B	24/06/82 26/03/84 06/06/82 11/06/82 23/06/82